Assessment report Part II – CZECHIA

## 1) ADMINISTRATIVE INFORMATION

| | |
|---|---|
| CT number | **2024-511188-26-00** |
| Member State Concerned | Austria Italy Belgium Czechia Spain France Netherlands Germany Poland |
| Title of the study | Randomizované otevřené klinické hodnocení fáze 3 zaměřené na porovnání účinnosti a bezpečnosti anitocabtagenu Autoleucel oproti standardní léčbě u účastníků s relabovaným/refrakterním mnohočetným myelomem<br>**A Phase 3, Randomized, Open-Label Study to Compare the Efficacy and Safety of Anitocabtagene Autoleucel Versus Standard of Care Therapy in Participants With Relapsed/Refractory Multiple Myeloma** |
| Name of sponsors | Kite Pharma Inc. |
| IMPs (repeat for PR1, PR2…..) | Substance (name/ code): CARFILZOMIB/SUB32911, BORTEZOMIB/SUB20020, DARATUMUMAB/SUB175772, POMALIDOMIDE/SUB33379, DARATUMUMAB/SUB175772, POMALIDOMIDE/SUB33379, CARFILZOMIB/SUB32911, POMALIDOMIDE/SUB33379, DARATUMUMAB/SUB175772, CARFILZOMIB/SUB32911, DEXAMETHASONE/SUB07017MIG, ANITOCABTAGENE AUTOLEUCEL/SUB359156, POMALIDOMIDE/SUB33379, BORTEZOMIB/SUB20020, BORTEZOMIB/SUB20020,<br>Marketing authorisation status (MA number, MS where authorised etc): EU/1/15/1060/001/EU, EU/1/19/1397/002/LI, EU/1/16/1101/002/EU, EU/1/13/850/004/EU, EU/1/16/1101/003/EU, EU/1/13/850/003/EU, EU/1/15/1060/003/EU, EU/1/13/850/001/EU, EU/1/16/1101/001/EU, EU/1/15/1060/002/EU, EU/1/15/1053/001/EU, null/null, EU/1/13/850/002/EU, EU/1/19/1397/003/EU, EU/1/19/1397/001/EU<br>Modified in relation to MA: |

| | |
|---|---|
| Has Part I been submitted prior to the submission of Part II? | Yes ☒ No ☐ |
| *If Yes* | |
| Is there already a conclusion on part I? | Yes ☐ No ☐ |
| Is the CT already approved in any member state? | Yes ☐ No ☐ |

## 2) GENERAL INFORMATION

| | |
|---|---|
| Is the CT a low-interventional trial?[1] | Yes ☐ No ☒ |
| First in man ☐, Phase I ☐, II ☐, III ☒, IV☐ NA☐ | |

[1] If yes – other demands for damage compensation, cfr. Art. 76

| | |
|---|---|
| Is the CT a cluster trial[2] | Yes ☐ No ☒ |
| Is the CT intended to be performed in more than one member states? | Yes ☒ No ☐ |
| Does the CT involve more than one site in the concerned member states? | Yes ☒ No ☐ |
| Does the CT include healthy volunteers? | Yes ☐ No ☒ |
| Does the CT include female? | Yes ☒ No ☐ |
| Male? | Yes ☒ No ☐ |
| Age group | |
| Adults (18-64 years) | Yes ☒ No ☐ |
| Elderly (>= 65 years) | Yes ☒ No ☐ |
| < 18 years | |
| In Utero | Yes ☐ No ☐ |
| Preterm Newborn Infants (up to gestational age < 37 weeks) | Yes ☐ No ☐ |
| Newborns (0-27 days) | Yes ☐ No ☐ |
| Infants and toddlers (28 days - 23 months) | Yes ☐ No ☐ |
| Children (2-11 years) | Yes ☐ No ☐ |
| Adolescents (12-17 years) | Yes ☐ No ☐ |
| Does the CT include vulnerable persons? | Yes ☐ No ☒ |
| *If yes* | |
| Minors | Yes ☐ No ☐ |
| Incapacitated subjects | Yes ☐ No ☐ |
| Pregnant women | Yes ☐ No ☐ |
| Breastfeeding women | Yes ☐ No ☐ |
| Subjects in emergency situations | Yes ☐ No ☐ |
| Other groups<br>If yes specify: ..... | Yes ☐ No ☐ |
| Are there study-specific procedures and/or interventions beyond the drug application? | Yes ☒ No ☐ |
| *If yes*<br><br>Specify: Blood, serum, fresh bone marrow aspirate, fresh bone marrow biopsy tissue, archival bone marrow aspirate, urine, plasmacytoma tissue.... | |

[2] If yes – other demands for informed consent, cfr. Art. 30

## 3) INFORMED CONSENT FORM
***(Repeat for ICF1, ICR2 ….)***

| | |
|---|---|
| Date/version of Informed Consent Form | Main ICF_CZ_Czech, v1.0_08Oct2024 |
| Does the Informed Consent Form contain the correct title of the CT? | Yes ☒ No ☐ |
| Does the Informed Consent Form contain placeholder for the dated signature of the person performing the interview? | Yes ☒ No ☐ |
| Does this placeholder indicate the qualification of the person performing the interview | Yes ☒ No ☐ |
| Does the Informed Consent Form contain a placeholder for<br><br>for the dated signature of the subject<br><br>for the dated signature of legally designated representative?<br><br>for the dated signature and name for an impartial witness (in case of a subject is not able to sign (temporarily disabled or illiterate)? | <br><br>Yes ☒ No ☐ NA ☐<br><br>Yes ☒ No ☐ NA ☐<br><br>Yes ☒ No ☐ NA ☐ |
| Does the Informed Consent Form contain a placeholder for the assent from minor (capable of forming an opinion) | Yes ☐ No ☐ NA ☒ |
| Does the subject or the legally designated representative declare that the information is understood? | Yes ☐ No ☐ NA ☒ |
| Does the subject or the legally designated representative confirm whether a copy of the Informed Consent Form (or the record) has been retained? | Yes ☒ No ☐ NA ☐ |
| Does the subject or the legally designated representative declare that the information is understood? | Yes ☒ No ☐ |
| *Additional items may be added according to national requirements*<br><br>For example<br><br>Does the subject or the legally designated representative confirm whether a copy of the Informed Consent Form (or the record) has been retained? | <br><br><br><br>Yes ☐ No ☐ |

**Updated documents:**

1) Main ICF_CZ_Czech, v1.0_08Oct2024

**Conclusion**

If all points are addressed Yes): The Inform Consent Form fulfils the conditions in art. 29, 1.

**Questions/queries:**

## 4) WRITTEN INFORMATION

| | |
|---|---|
| Is the Information sheet sufficiently comprehensive, concise, clear, relevant, and understandable to a layperson? | Yes ☒ No ☐ |
| Does the information sheet describe adequately nature, objectives, benefits, implications, risks, and inconveniences, of the clinical trial? | Yes ☒ No ☐ |
| Does the information sheet adequately describe the subject's rights and guarantees regarding his or her protection, in particular his or her right to refuse to participate and the right to withdraw from the clinical trial at any time without any resulting detriment and without having to provide any justification ? | Yes ☒ No ☐ |
| Does the information sheet adequately explain that withdrawal of the informed consent will not affect the results of activities already carried out and the use of data obtained, based on informed consent, before its withdrawal? | Yes ☒ No ☐ |
| Does the information sheet adequately describe the conditions under which the clinical trial is to be conducted, including the expected duration of the subject's participation in the clinical trial? | Yes ☒ No ☐ |
| Does the information sheet adequately describe | |
| the possible treatment alternatives, | Yes ☒ No ☐ |
| the follow-up measures if the participation of the subject in the clinical trial is discontinued | Yes ☒ No ☐ |
| Post trial treatment options | Yes ☒ No ☐ NA ☐ |
| Does the information sheet provide information about the damage compensation according to national law of concerned member state | Yes ☒ No ☐ NA ☐ |
| *Further detailed points to be filled in at a national level* | |
| *If NA* | |
| Does the information sheet adequately inform that no particular arrangements for damage compensation are in place | Yes ☐ No ☐ |
| Does the information sheet provide | |
| the EU trial number | Yes ☒ No ☐ |
| information about the availability of the clinical trial results (that the summary of the results of the clinical trial and a summary presented in terms understandable to a layperson will be made available in the | Yes ☒ No ☐ |

| EU database) | |
|---|---|
| Does the information sheet provide adequate information about planned personal data collection and processing | Yes ☒ No ☐ |
| Does the information sheet provide adequate information about planned collection, storage and future use of biological samples? | Yes ☒ No ☐ |
| *Further detailed points must filled in by member states at national level*<br>(in accordance with Regulation (EC) No 45/2001 and **national data protection legislation** implementing Regulation (EU) 2016/679, respectively) | |

| | |
|---|---|
| In the case of a trial with minors.<br>Is there Informed Consent documents adequately paying attentions to the information needs of these subjects? | Yes ☐ No ☐ |
| In the case of a trial with incapacitated subjects.<br>Is there Informed Consent documents adequately paying attentions to the information needs of these subjects? | Yes ☐ No ☐ |
| In the case of a trial in an emergency situation<br>Are there Informed Consent documents to obtain consent from the subject and/or legally designated representative to continue the participation of the subject in the CT after the intervention? | Yes ☐ No ☐ |

**Conclusion**

If all points are addressed Yes: The written information fulfils the conditions in art. 28 and 29

**Questions/queries:**

## 5) PROTECTION OF PERSONAL DATA

| | |
|---|---|
| Has a statement been submitted by the sponsor or his or her representative that data will be collected and processed in compliance with Regulation (EC) No 45/2001 and **national data protection legislation** implementing Regulation (EU) 2016/679, respectively | Yes ☒ No ☐ |
| *Further detailed points must filled in by member states at national level* | Yes ☒ No ☐ |
| For example | |
| Are the rules for the collection, storage and future use of biological samples of the subject fulfilled? | Yes ☒ No ☐ |
| Is the procedure to pseudonymise the data correct? | Yes ☒ No ☐ |
| Are Initials omitted? | Yes ☒ No ☐ |
| Is there no placeholder for the complete birthday? | Yes ☒ No ☐ |
| Will the coding number maintained in the hand of the investigator or of a trustee? | Yes ☒ No ☐ |

| | |
|---|---|
| Is described how long the data will be stored? | Yes ☒ No ☐ |
| Is there a comprehensive description of the aims and scope of data collection? | Yes ☒ No ☐ |
| Is there an indication, whether the data will be transferred to a so called "third party country" with a reduced level of data protection? | Yes ☒ No ☐ |
| Will the subject (or his or her legally designated representative) be asked to consent to the use of his or her data and/or biological samples outside the protocol of the clinical trial for other scientific purposes? | Yes ☐ No ☒ |
| *If Yes*<br>Will the subject be informed that this consent may be withdrawn at any time by the subject or his or her legally designated representative? | Yes ☐ No ☐ |

**Questions/queries:**

## 6) COMPENSATION

| | |
|---|---|
| Is there no undue influence, including that of a financial nature, exerted on subjects to participate in the clinical trial | Yes ☐ No ☒ |
| In trials with incapacitated subjects, minors, pregnant or breastfeeding subjects:<br>Are no incentives or financial inducements given to the subjects or their legally designated representatives, except for compensation for expenses and loss of earnings directly related to the participation in the clinical trial; | Yes ☐ No ☐ NA ☒ |

**Questions/queries:**

## 7) RECRUITMENT

| | |
|---|---|
| Is the procedure for inclusion of subjects described in detail in the protocol or a separate document | Yes ☒ No ☐ |
| Is clearly described of what the first act of recruitment is? | Yes ☐ No ☐ |
| Is the recruitment of subjects planned to be done through advertisement | Yes ☐ No ☐<br>Yes ☐ No ☒ |
| If yes:<br>Have copies of the advertising material been submitted, including any printed materials, and audio or visual recordings. | Yes ☐ No ☐ |
| Has an outline of the procedures proposed for handling responses to the advertisement been submitted?<br>Have copies of communications used to invite subjects to participate in the clinical trial been submitted?<br>Have arrangements for information or advice to the respondents found not to be suitable for inclusion in the clinical trial been | Yes ☐ No ☐ |

| | |
|---|---|
| described? | Yes ☐ No ☐ |
| Does the person performing the interview has the required qualification according to the law of concerned member states | Yes ☐ No ☐ |
| Are the arrangements for recruitment of subjects adequate? | Yes ☐ No ☐ |

**Questions/queries:**

## 8) SUITABILITY OF THE INVESTIGATOR

| | |
|---|---|
| 1) prof. MUDr. Roman Hájek, CSc., Fakultní nemocnice Ostrava, Klinika hematoonkologie, 17.listopadu 1790/5, 708 00 Ostrava<br>2) prof. MUDr. Luděk Pour, Ph.D., Fakultní nemocnice Brno, Interní hematologická a onkologická klinika, Jihlavská 340/20, 625 00 Brno | |
| Is there an informative CV? | Yes ☒ No ☐ |
| Is previous experience obtained from work with clinical trials described? | Yes ☒ No ☐ |
| Is previous experience obtained from work with patient care described? | Yes ☒ No ☐ |
| Have certificates describing adequate ICH/GPV training been submitted? | Yes ☒ No ☐ |
| Has a financial disclosure been submitted? | Yes ☐ No ☐ NA ☒ |
| Have institutional affiliations, that might influence the impartiality of the investigators been presented? | Yes ☒ No ☐ |
| *Further detailed points may be filled in by member states at national level*<br><br>For example<br><br>Is the investigator qualified in accordance with national Low? *(medical doctor as defined in national law, or a person following a profession which is recognised in the Member State concerned)* | Yes ☐ No ☐ |

**Conclusion –** PIs are approved

1) prof. MUDr. Roman Hájek, CSc., Fakultní nemocnice Ostrava, Klinika hematoonkologie, 17.listopadu 1790/5, 708 00 Ostrava
2) prof. MUDr. Luděk Pour, Ph.D., Fakultní nemocnice Brno, Interní hematologická a onkologická klinika, Jihlavská 340/20, 625 00 Brno

**Reason:**

## 9) SUITABILITY OF THE FACILITIES

| | |
|---|---|
| Has a list of the planned clinical trial sites with name and position of the principal investigators | Yes ☒ No ☐ |
| and the planned number of subjects at the sites been submitted? | Yes ☒ No ☐ |
| Fakultní nemocnice Ostrava, Klinika hematoonkologie, 17.listopadu 1790/5, 708 00 Ostrava<br>Fakultní nemocnice Brno, Interní hematologická a onkologická klinika, Jihlavská 340/20, 625 00 Brno | |
| Has a written statement been submitted describing the suitability of the clinical trial sites adapted to the nature and use of the investigational medicinal product?<br>(issued by the head of the clinic/institution at the clinical trial site or by some other responsible person, according to the system in the Member State concerned) | Yes ☒ No ☐ |
| Does this statement adequately describe | |
| the suitability of facilities, | Yes ☒ No ☐ |
| the equipment, | Yes ☒ No ☐ |
| the human resources | Yes ☒ No ☐ |
| the expertise of the site, | Yes ☒ No ☐ |

**Conclusion –** trial sites are approved:

1) Fakultní nemocnice Ostrava, Klinika hematoonkologie, 17.listopadu 1790/5, 708 00 Ostrava - prof. MUDr. Roman Hájek, CSc.
2) Fakultní nemocnice Brno, Interní hematologická a onkologická klinika, Jihlavská 340/20, 625 00 Brno - prof. MUDr. Luděk Pour, Ph.D.

**Reason:**

## 10) PROOF OF INSURANCE COVER OR INDEMNIFICATION

| | |
|---|---|
| Is the arrangement for damage compensation in accordance to **national law**? | Yes ☒ No ☐ |
| *Further detailed points must be filled in at the national level* | |

**Questions/queries:**

## 11) FINANCIAL AND OTHER ARRANGEMENTS

| | |
|---|---|
| Is there a description confirming adequate financing of the clinical trial is ensured? | Yes ☐ No ☐ |
| Are financial transactions and compensation paid to subjects adequate? | Yes ☐ No ☐ |

| | |
|---|---|
| Are financial transactions and compensation paid to the investigator/site for participating in the clinical trial adequate? | Yes ☐ No ☐ |
| Are any other agreement between the sponsor and the site adequate? | Yes ☐ No ☐ |

**Questions/queries:**

## 12) LIST OF QUESTIONS TO THE SPONSOR/

## 13) ASSESMENT OF THE SPONOR´S RESPONSE

| | |
|---|---|
| Are all queries resolved? | Yes ☒ No ☐ |
| If not specify: | |

## 14) FINAL DECISION

| | |
|---|---|
| The Clinical trial is approvable | ☒ |
| The Clinical trial is not approvable | ☐ |
| The Clinical trial is approvable subjects to conditions | ☐ |

**The approval is valid for the following trial sites and investigators**

**List of trial sites and investigators**

1. Fakultní nemocnice Ostrava, Klinika hematoonkologie, 17.listopadu 1790/5, 708 00 Ostrava - prof. MUDr. Roman Hájek, CSc.,
2. Fakultní nemocnice Brno, Interní hematologická a onkologická klinika, Jihlavská 340/20, 625 00 Brno - prof. MUDr. Luděk Pour, Ph.D.,

**List of documents on the basis of which the decision was made**

1. D4_Patient facing documents_questionnaire_EN_EQ 5D 5L Paper Self-Complete, Czech,
2. D4_Patient facing documents_questionnaire_CZ_EORTC QLQ_MY20
3. D4_Patient facing document_questionnaire_CZ_EORTC QLQ-C30
4. K1_KT-US-679-0788_Recruitment_Informed-Consent-Procedure_CZ_13Jun2024
5. L1_KT-US-679-0788_Main ICF_CZ_Czech, v1.0_08Oct2024
6. L1_KT-US-679-0788_GDPR ICF_CZ_Czech_v1.0_19Jun2024
7. L1_KT-US-679-0788_Optional Biopsy ICF_CZ_Czech_v1.0_19Jun2024
8. L1_KT-US-679-0788_Optional Future Research ICF_CZ_Czech_v1.0_19Jun2024
9. L1_KT-US-679-0788_Pregnant Participant FUL_ ICF_CZ_Czech_v1.0_19Jun2024
10. L1_KT-US-679-0788_Pregnant Partner FUL_ ICF_CZ_Czech_v1.0_19Jun2024
11. L1_KT-US-679-0788_Scout ICF_CZ_Czech_v1.0_09Jul2024
12. L1_KT-US-679-0788_Scout Telephone Data ICF_CZ_Czech_v1.0_09Jul2024
13. L2_KT-US-679-0788_Table of Visits and Procedures_CZ_Czech_v1.0_19Jun2024
14. M1_CV_PI_Hajek-Roman_FN-Ostrava_CZ_04Jul2024
15. M1_CV_PI_Pour-Ludek_FN-Brno_CZ_08Jul2024
16. M2_KT-US-679-0788_Declaration-of-interest_Hajek-Roman_PI_FN Ostrava_CZ_04Jul2024
17. M2_KT-US-679-0788_Declaration-of-interest_Pour-Ludek_PI_FN Brno_CZ_08Jul2024
18. N1_KT-US-679-788_Statement-of-Suitability_CZ_Hajek_04Jul2024

19. N1-KT-US-679-0788 (iMMagine-3)_Czechia_List of Documents_17Jul2024
20. N1_KT-US-679-788_Statement-of-Suitability_CZ_Pour_08Jul2024
21. N1_ToC_List of Documents_priloha podani_16Oct2024
22. N2_KT-US-679-788_List_of_participating sites_CZ_01Jul2024
23. O1_KT-US-679-0788_Insurance-Certificate_CZ_21Jun2024
24. O2_KT-US-679-0788_Insurance_Sponsor_Statement_CZ_01Jul2024
25. O2_KT-US-679-0788_Insurance_Terms Conditions_CZ_Czech_01Jan2020
26. P1_KT-US-679-788_Compensation_for_Trial_Participants_v1.0_24May2024
27. P1_KT-US-679-0788_Financial_Coverage_sponsor_Statement_CZ_01Jul2024
28. R1_KT-US-679-0788_Data-Protection-Declaration_CZ_01Jul2024
29. S1_KT-US-679-0788_Use-of-Biological-samples-Declaration_CZ_v1.0_17Jun2024

**List of members of the ethic committee participating in the decision**

MUDr. Jindřiška Burešová (chairman)
doc. MUDr. Jiřina Zapletalová, Ph.D.
prof. MUDr. et Mgr. Jiří Minařík, Ph.D.
MUDr. Libor Kvapil
MUDr. Josef Srovnal, Ph.D.
Anna Holá
MUDr. et PhDr. Lenka Hansmanová, Ph.D.
PharmDr. Tomáš Anděl, Ph.D.
doc. MUDr. Libuše Stárková, CSc.
prof. MUDr. Karel Indrák, DrSc.
MUDr. Karel Cwiertka, Ph.D.
MUDr. Jan Strojil, Ph.D.
Pavel Stuška, ThLic., PhD.
MUDr. Renata Lubičová
Ing. Jakub Král
Iveta Sudolská
Věra Bartlová

**In Prague November 5th, 2024**